Application No.: 10/698,213 Reply to Office Action of: October 3, 2006

## CLAIMS

The current claim set of the application is presented below. Indications as to the status of the claims appear in parentheses after the claim number. Deletions are identified in double brackets or strikethrough (e.g. [[deletion]] or deletion) and new text is identified with double underlining (e.g. new language).

1. (Currently Amended) A method of delivering a denervating agent to a prostate gland comprising:

inserting an imaging apparatus into a rectum of a patient;
generating one or more images of a prostate gland via the imaging apparatus;
inserting a <u>spring loaded</u> needle through a perineum <u>of</u> the patient;

positioning a distal end of the <u>spring loaded</u> needle in proximity to the prostate gland at a <u>first location</u> based on the one or more images:

actuating a <u>spring</u> mechanism to cause the distal end of the <u>spring loaded</u> needle to spring bias into the prostate gland; and

delivering a <u>dose of a</u> denervating agent to the prostate gland <u>at the first location</u> via a humen of the <u>spring loaded</u> needle.

- 2. (Currently Amended) The method of claim 1, wherein <u>generating one or more images of</u>
  the <u>prostate gland further the imaging apparatus</u> comprises <u>generating one or more images using</u>
  an ultrasonic imaging device.
- 3. (Original) The method of claim 2, further comprising maneuvering the ultrasonic imaging device to generate the one or more images of the prostate gland.
- 4. (Currently Amended) The method of claim 1, wherein the delivering a dose of a denervating agent includes delivering a dose of botulinum toxin.
- 5. (Currently Amended) The method of claim 1, further comprising: actuating the mechanism to cause the distal and of the needle to spring bias into the prostate gland at a first location:

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————delivering a first dose of the denervating agent to the prostate gland via the lumen of the needle;

removing the distal end of the needle from the prostate gland at the first location;

positioning the distal end of the needle in proximity to a second location of the prostate gland based on the one or more images;

actuating the <u>spring</u> mechanism again to cause the distal end of needle to spring bias into the prostate gland at the second location; and

delivering a second dose of the denervating agent to the prostate gland via the lumen of the needle.

6. (Currently Amended) The method of claim 5, further comprising: removing the distal end of the needle from the prostate gland at the second location; positioning the distal end of the needle in proximity to a third location of the prostate gland based on the one or more images;

actuating the <u>spring</u> mechanism again to cause the distal end of needle to spring bias into the prostate gland at the third location; and

delivering a third dose of the denervating agent to the prostate gland via the lumen of the needle.

7. (Currently Amended) The method of claim 6, further comprising: removing the distal end of the needle from the prostate gland at the third location; positioning the distal end of the needle in proximity to a fourth location of the prostate gland based on the one or more images;

actuating the <u>spring</u> mechanism again to cause the distal end of needle to spring bias into the prostate gland at the fourth location; and

delivering a fourth dose of the denervating agent to the prostate gland via the lumen of the needle.

8. (Original) The method of claim 7, wherein each of the doses comprise approximately 0.5 milliliter of botulinum toxin.

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- 9. (Original) The method of claim 1, further comprising delivering the denervating agent from a denervating agent delivery assembly that includes a reservoir to hold the denervating agent and an actuator to cause the denervating agent to flow from the reservoir through the lumen, wherein a hub and a fluid line attaches the reservoir to the needle.
- 10. (Original) The method of claim 1, further comprising delivering the denervating agent from a denervating agent delivery assembly that includes a first reservoir that holds a substantial amount of the denervating agent, a second reservoir to hold a first discrete dose of the denervating agent and an actuator to cause the denervating agent to flow from the second reservoir through the lumen, wherein a hub attaches the second reservoir to the needle and the second reservoir refills with a second discrete dose of the denervating agent from the first reservoir following delivery of the first discrete dose.
- 11. (Currently Amended) A system for delivering a denervating agent to a prostate gland comprising:

an imaging apparatus sized for insertion into a rectum of a patient to generate one or more images of a prostate gland;

- a <u>spring loaded</u> needle for insertion through a perineum of the patient in proximity to the prostate gland based on the one or more images, the needle defining a lumen; and
- a spring mechanism to bias the needle into the prostate gland upon actuation such that a denervating agent can be delivered to the prostate gland through the lumen.
- 12. (Original) The system of claim 11, further comprising an actuator to actuate the spring mechanism to bias the needle into the prostate gland.
- 13. (Original) The system of claim 11, further comprising a denervating agent delivery assembly coupled to the needle to deliver the denervating agent through the lumen.
- 14. (Original) The system of claim 13, wherein the denervating agent delivery assembly includes a reservoir to hold the denervating agent and an actuator to cause the denervating agent to flow from the reservoir through the lumen.

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15. (Original) The system of claim 14, wherein the second actuator comprises a plunger.

- 16. (Original) The system of claim 14, wherein further comprising a hub and a fluid line for attachment of the needle to the reservoir.
- 17. (Original) The system of claim 13, wherein the denervating agent delivery assembly includes a first reservoir to hold a substantial amount of the denervating agent, a second reservoir to hold a discrete dose of the denervating agent, and an actuator to cause the denervating agent to flow from the second reservoir through the lumen, wherein the second reservoir refills with another discrete dose of the denervating agent from the first reservoir following actuation of the second actuator.
- 18. (Original) The system of claim 13, wherein the denervating agent delivery assembly includes a second actuator, a pump and a reservoir, wherein upon actuation of the second actuator the pump causes delivery of the denervating agent from the reservoir through the lumen.
- 19. (Original) The system of claim 11, wherein the denervating agent includes botulinum toxin.
- 20. (Original) The system of claim 11, wherein the imaging apparatus comprises an ultrasonic imaging apparatus.
- 21. (Original) The system of claim 11, wherein the needle includes a hyper-echoic coating.
- 22. (Currently Amended) A system for delivering a denervating agent to a prostate gland comprising:

an imaging apparatus sized for insertion into a rectum of a patient to generate one or more images of a prostate gland;

a <u>spring loaded</u> needle for insertion through a perineum of the patient in proximity to the prostate gland based on the one or more images, the needle defining a lumen, wherein the spring

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loaded needle is operably attached to a wheel to permit rotation of the needle to a desired orientation relative to the prostrate gland; and

means for spring-biasing the needle into the prostate gland such that a denervating agent can be delivered to the prostate gland through the lumen.

- 23. (Original) The system of claim 22, further comprising means for delivering the denervating agent through the lumen.
- 24. (New) A method of delivering a denervating agent to a prostate gland comprising: inserting an imaging apparatus into a rectum of a patient; generating one or more images of a prostate gland via the imaging apparatus; inserting a spring loaded needle through a perincum of the patient, the spring loaded needle extending through a shaft;

positioning a distal end of the spring loaded needle in proximity to the prostate gland based on the one or more images;

actuating a spring mechanism to cause the distal end of the needle to spring bias into the prostate gland at a first location;

delivering a first dose of the denervating agent to the prostate gland via the lumen of the needle;

repositioning the distal end of the needle in proximity to a second location of the prostate gland based on the one or more images, wherein repositioning the spring loaded needle includes rotating the needle by actuation of a wheel;

actuating the spring mechanism again to cause the distal end of needle to spring bias into the prostate gland at the second location; and

delivering a second dose of the denervating agent to the prostate gland via the lumen of the needle.